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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,759	02/24/2004	Amir Abolfathi	AT-000220	2843

24710 7590 07/18/2005

ALIGN TECHNOLOGY, INC.
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SANTA CLARA, CA 95050

EXAMINER

BUMGARNER, MELBA N

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,759

Applicant(s)

ABOLFATHI ET AL.

Examiner

Melba Bumgarner

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/6/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 22 is objected to because of the following informalities: "the arch expanded" should read --the arch expander--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 7, 11-13, 16-18, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Truax et al. (5,242,304). Truax et al. disclose a method for making an arch expander 38 comprising acquiring a digital scan representing the mouth of the patient (column 5 line 44), fabricating a first portion 58 having a plurality of cavities for receiving posterior teeth on one side and a palatal portion and a second portion 60 having a plurality of cavities for receiving posterior teeth on an opposite side and a palatal portion 60, coupling an expansion member 48, each of the plurality of cavities configured to fit over the posterior teeth (figure 6). The method comprises adjusting the expansion member to vary the spacing 50 between the portions. The expansion member comprises one or more screws 52. The scan comprises intra-oral scanning. Truax et al disclose a dental appliance comprising a first portion 58 having a plurality of cavities for receiving posterior teeth 43 on one side of the palate and a palatal portion

extending toward a centerline of the palate, a second portion 60 having a plurality of cavities for receiving posterior teeth on an opposite side of the palate and a palatal portion, the portions including at least one layer of a polymeric material (column 6 line 41), and an expander 48 coupled between the first and second portions, the plurality of cavities configured to fit over the posterior teeth. Patentable weight is not given to the process and the intermediate products used in the process by which the dental appliance is made, because a product claim is properly met if the final product is shown regardless of the process used. The dental appliance is removable and replaceable. Truax et al. show placing the arch expander in the patient's mouth.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truax et al. in view of Williams (5,769,631). Truax et al. disclose a method and dental appliance that shows the limitations as described above; however, they do not show expansion member comprising springs. Williams teaches a dental appliance having an expansion member comprising one or more springs 138. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the expansion member of Truax et al. with the spring of Williams as Truax et al. shows that a variety of expansion joints or other adjustment mechanisms may be incorporated into the dental appliance (column 7 line 63).

Furthermore, the specification also states that the expander may be a screw, spring, or any adjustable device that increases or decreases the separation of the portion.

6. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truax et al. in view of Pepper (5,376,001). Truax et al. disclose a method and dental appliance that shows the limitations as described above; however, they do not show the first and second portions comprising nitinol. Pepper teaches a dental appliance having expander portions comprising nitinol (column 6 line 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the portions of Truax et al. with the nitinol of Pepper as Truax et al. shows that a variety of expanders or other adjustment mechanisms may be incorporated into the dental appliance (column 7 line 63). Furthermore, the specification also states that the expander may be any adjustable device that increases or decreases the separation of the portion.

7. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truax et al. in view of Schulman et al. (6,808,659). Truax et al. disclose a method and dental appliance that shows the limitations as described above; however, they do not show the appliance (column 3 line 28) fabricated using stereolithography, fused deposition modeling, 3-D printing or selective laser sintering. Schulman et al. teach a method comprising the appliance fabricated using stereolithography, fused deposition modeling, 3-D printing or selective laser sintering. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Truax et al. with the fabrication of Schulman et al. in order to produce an appliance that is homogeneous and has high strength and reliability in view of Schulman et al. Schulman et al. show the scanning comprising taking an impression of the

patient's teeth, placing the impression in a scanner and generating a 3-D model of the impression (column 10 line 56).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Truax et al. Truax et al. disclose a dental appliance that shows the limitations as described above; however, they does not show the plurality of cavities configured to retain the dental appliance without requiring brackets or other fixtures to be adhered to the patient's teeth. It would have been an obvious matter of choice to one of ordinary skill in the art as to whether brackets or other fixtures are adhered to the teeth. The specification does not disclose such a function as critical to the claimed invention, see below.

Response to Arguments

9. Applicant's arguments filed May 6, 2005 have been fully considered but they are not persuasive. The prior art show the limitations of the method and product of the claimed invention. It is believed that the appliance of the prior art is custom fitted in that is it made to conform to a specific mouth, and the term "custom-fit" is, likewise, not presented nor defined in applicant's specification. It is noted that the applicant does not disclose the portions of the appliance configured to be retained without requiring brackets or other fixtures adhered to the teeth. In fact, the specification discloses the engagement of the dental appliance with undercuts and anchors, and the cavities of the portions including a receptacle or aperture intended to accommodate an anchor placed on a tooth.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, reading "Melba Bumgarner".

Melba Bumgarner
Primary Examiner